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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/671,731	09/29/2003	Takahiro Imada	K-1970DIV	6740

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 10/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/671,731	IMADA ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 August 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 8/31/06 is acknowledged. Claims 1-7 are being considered on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No basis or support is found in the present specification for the introduction into any plant any fungus or even any *Neotyphodium* that infects the plant and that is selected to produce chanoclavine as a final metabolic product wherein yield of further metabolic product through the chanoclavine is absent, and wherein chanoclavine is accumulated in plant tissue. The only plants infected in this manner are certain grasses and particular strains of the fungus. Please note the comparative tests done by applicants even regarding the specific grasses.

Therefore, this material constitutes new matter and should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to any plant that accumulates chanoclavine in plant tissue, which plant comprises a symbiotic fungus that produced chanoclavine, and wherein the

symbiotic fungus may be any fungus or *Neotyphodium* or specific strains of *Neotyphodium* "selected" to produce chanoclavine as a final metabolic product and wherein chanoclavine is accumulated in plant tissue. In contrast, the specification only provides guidance for certain specific plants comprising the endophytic strains *Neotyphodium.* FERM P-17672 *(Neotyphodium sp.* Po-060B), FERM P-17673 *(Neotyphodium sp.* Po-062), and FERM P-17674 *(Neotyphodium sp. Po-120).* No guidance is presented regarding the structure/function relationship between any plant whatsoever, including mosses, algae, pine trees, oaks, cacti or begonias, for example, comprising any fungus and the accumulation of chanoclavine in the plant tissue. The disclosed species is not representative of the genus of plants that have chanoclavine in their tissues, because there is no known correlation between plants comprising a fungus or *Neotyphodium* and the functional limitation of the claimed plant as accumulating chanoclavine in its tissues that one of skill in the art would recognize. There is no clear indication that detection of chanoclavine in the plant tissue occurs in all plants comprising fungi or comprising *Neotyphodium* or even comprising the specific fungi *Neotyphodium* FERM P-17672 *(Neotyphodium sp.* Po-060B), FERM P-17673 *(Neotyphodium sp.* Po-062), and FERM P-17674 *(Neotyphodium sp. Po-120).* Thus it is not apparent that the disclosure provided is reasonably predictive of the activity of plants obtained as claimed. No guidance is presented regarding the evaluation of "accumulation of chanoclavine in plant tissue" and the production of chanoclavine as a final metabolic product by fungi.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague, indefinite and confusing in the recitation of "said symbiotic fungus being selected to produce chanoclavine as a final metabolic product, wherein yield of further metabolic product through the chanoclavine is absent". First, the claim appears incomplete in

that the selection steps are absent in the product by process. Thus it is unclear how the fungus is "selected". Second, the meaning of the phrase "wherein yield of further metabolic product through the chanoclavine is absent" cannot be readily ascertained in this context. It is unclear, for example, whether this yield pertains to the plant or in to the fungus. No new matter may be added.

Claim 1 is vague, indefinite and confusing in the recitation of "said symbiotic fungus producing chanoclavine as **a final metabolic product**". The nature of "a final metabolic product" is uncertain, since this implies that there are many "final metabolic products".

Claim 5 is confusing since the cannot be determined whether the plant or the seed are subjected to artificial introduction of the symbiotic fungus. If it is the seed, this appears redundant if the plant is, in fact, symbiotically infected with the fungus.

Claim 6 is confusing in the recitation of "wherein said plant comprises a plant...". Amendment to "wherein said plant is a plant..." would be remedial.

Claim 7 is vague and indefinite in that the plant intended by "said plant is a hybrid plant having a parent comprising the plant or a seed thereof ...", since it is unclear whether the hybrid is or is not infected by the symbiotic fungus.

To clarify the invention and for the sake of consistency, the claims and specification should be amended to recite the respective Budapest deposit numbers (FERM BP) of the strains of claim 3. The genus of the deposited strain should be inserted in the claim to clarify the invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, and 4-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Porter *et al.*

The claims are broadly drawn to any plant that accumulates chanoclavine in plant tissue, which plant comprises a symbiotic fungus that produced chanoclavine "selected" to produce

chanoclavine as a final metabolic product and wherein chanoclavine is accumulated in plant tissue.

Porter discloses a plant which is infected with an endophyte that produces chanoclavine. It can reasonably presumed that the chanoclavine produced is found in the plant tissue at least to some extent upon infection.

It is deemed that the process of infection or the process by which the plant is obtained does not affect the product. (See, e.g., page 874). It is noted that ryegrass belongs to the genus *Lolium.*

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the

applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Cagas *et al.* or Petroski *et al.*.

The claims are broadly drawn to any plant that accumulates chanoclavine in plant tissue, which plant comprises a symbiotic fungus that produced chanoclavine, and wherein the symbiotic fungus may be any fungus or *Neotyphodium* or specific strains of *Neotyphodium* "selected" to produce chanoclavine as a final metabolic product and wherein chanoclavine is accumulated in plant tissue.

Cagas *et al.* discloses a plant which is infected with an endophyte that produces chanoclavine, such as *Neotyphodium*. It is deemed that the process of infection or the process by which the plant is obtained does not affect the product. (See, e.g., page 366). It is noted that plants such as *Lolium* and *Festuca* are infected. It can reasonably presumed that the chanoclavine produced is found in the plant tissue at least to some extent upon infection.

Petroski *et al.* discloses a plant which is infected with an endophyte that produces chanoclavine such as *Acremonium (Neotyphodium)*. It is deemed that the process of infection or the process by which the plant is obtained does not affect the product. (See, e.g., page 86). It can reasonably presumed that the chanoclavine produced is found in the plant tissue at least to some extent upon infection.

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted) (Claim was directed to a Novolac color developer. The process of making the developer was allowed. The difference between the inventive process and the prior art was the addition of metal oxide and carboxylic acid as separate ingredients instead of adding the more expensive pre-reacted metal carboxylate. The product-by-process

claim was rejected because the end product, in both the prior art and the allowed process, ends up containing metal carboxylate. The fact that the metal carboxylate is not directly added, but is instead produced in-situ does not change the end product.).

Furthermore, the composition is claimed as a product-by-process. Since the U.S. Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant argues that the amendments require the fungus to produce chanoclavine as the final metabolic product and for "further metabolic generation to be absent". However, this is incorrect. The claims are directed to the production of chanoclavine as a final product. The terminology "metabolic generation" does not appear to be terminology art and the meaning intended is not ascertainable.. The claim is directed to "wherein yield of further metabolic product through the chanoclavine is absent", which is also unclear. Does this refer to the plant not making any products other than chanoclavine or does it refer to the fungus not making any products other than chanoclavine? See also the rejection under 35 U.S.C § 112.

The arguments directed to the sole production of chanoclavine as the final product appears to pertain to the three *Neotyphodium* strains isolated by applicant. However, they are not

clearly pertinent to the plant claimed. There is nothing on the as filed specification to indicate or suggest the effects of any fungus or any *Neotyphodium* on the metabolism of any plant, or even for the three *Neotyphodium* strains isolated by applicant.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner